Regulatory submission query form for human medicines

This form should be used when advice on a human regulatory submission is required and where the published guidance does not offer sufficient information on the topic. The query should concern issues with Module 1 of the eCTD submission documentation for human medicines.

The completed form should be submitted as a Microsoft Word document to facilitate the inclusion of the response. Please send the completed form to [submissions@hpra.ie](mailto:submissions@hpra.ie). The target response time for queries submitted with this form is two weeks from the date of receipt of the form.

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| 1. Contact and product details   Contact name and position  Company and address  Contact telephone number  Contact email address  Product name and INN  PA number |

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| 1. previous correspondence   Previous HPRA assessment case number (if relevant):    Previous HPRA correspondence in relation to the query (add attachments if relevant): |

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| 1. query   Relevant background information to the query:    Specific query: |

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| 1. HPRA RESPONSE     Date of response:  *Note: The HPRA response is based solely on the information provided in this form.* |